



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA-2011-F-0172]

Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food

Establishments; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments--Small Entity Compliance Guide”. The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled “Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.”

DATES: The SECG will be available as of [Insert date of publication in the Federal Register].
Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the SECG to the Office of Nutrition, Labeling and Dietary Supplements, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in

processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the SECG.

Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written comments on the SECG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel Y. Reese, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 1, 2014 (79 FR 71156), we issued a final rule requiring nutrition labeling of standard menu items in restaurants and similar retail food establishments (the final rule). The final rule, which is codified at 21 CFR 101.11, is effective December 1, 2015.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents our current thinking on nutrition labeling of standard menu items in restaurants and similar retail food establishments. It does not create or confer any

rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This SECG refers to collections of information described in FDA's final rule that published in the Federal Register of December 1, 2014 (79 FR 71156), and that will be effective on December 1, 2015. As stated in the final rule, these collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). In compliance with the PRA (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of the final rule to OMB for review. FDA will publish a document in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Comments

Interested persons may submit either electronic comments regarding the SECG to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the SECG at either

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: March 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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